

Remarks

Claims 18-47 are pending in the present application. Claims 18-34 were of record, and new claims 35-47 are presented. Support for added claims 35-47 is found throughout the specification.

(1) Rejection under 35 U.S.C. 112, second paragraph.

In the Office action of October 6, 2006, claim 25 was rejected for being vague and indefinite in the use of the term, "essential plant oil." The Examiner acknowledges that applicants have provided examples of such essential plant oils, but states that "it is unclear what constitutes 'an essential plant oil' and how one may distinguish between 'an essential plant oil' and other oils obtainable from plants, such as vegetable oils."

However, the term "essential oil" of a plant is a recognized technical term appearing in Hawley's Condensed Chemical Dictionary (Eighth Edition) (copy attached), and which the Office has already accepted as proper claim terminology in numerous issued patents (see attached USPTO search page). Accordingly, applicants believe that this is a term that would be well-understood to a worker in the pharmaceutical art, particularly when read in the context of applicants' disclosure (e.g., Par. 25 of the published application). Accordingly, applicants respectfully request that this ground of rejection be withdrawn.

(2) Rejection under 35 U.S.C. 103(a).

Claims 18-24 and 26-34 of record were rejected as being obvious over Greve et al. (U.S. Patent No. 5,801,199) (hereinafter, "Greve et al.") in view of Jacob et al. (US 2003/0060486) ("Jacob et al.").

Greve et al. teach a "synergistic effect" (col. 1, ll. 58-59) in treating rhinitis with the combination of two active agents previously employed in single-ingredient preparations, i.e. (1) an α -sympathomimetic compound having a 2-imidazoline structure (e.g., xylometazoline, oxymetazoline), and (2) a pantothenic compound. According to Greve et al., this combination overcomes the "rebound effect" associated with repeated use of oxymetazoline or xylometazoline as a monotherapy (col. 5, ll. 49; col. 6, ll. 18-29).

However, as the Examiner acknowledges, other than using the same 2-imidazoline actives as applicants, the Greve et al. reference is totally devoid of teaching concerning the required additional components of applicants' formulations, i.e.: (1) the mucopolysaccharide and (2) polypropylene glycol. If anything, Greve et al. teach that the therapeutic value of

oxymetazoline or xylometazoline without a pantothenol is "severely limited" (col. 5, l. 45; col. 6, ll. 22-23).

The Examiner relies on Jacob et al. to supply the deficiencies of Greve et al.

Jacob et al. provide a broad brush disclosure of "mucoadhesive" polymers to be used with or without a pharmacological active in the treatment of mucosal diseases:

[0069] "A linear or cross-linked polymer polyanionic or polycationic polymer which may or may not already be known to provide mucoadhesion. Such polymers include (but are not limited to) linear polyacrylic acid, a cross-linked homopolymer based on acrylic acid, a crosslinked copolymer based on acrylic acid, linear methacrylic acid homopolymers and copolymers, carboxymethylcellulose, hydroxyalkylcellulose, dextran sulfate, dermatan sulfate, and hyaluronic acid. Other mucoadhesive polymers are well-known to those skilled in the art. The mucoadhesive formulations of the current invention can contain a single mucoadhesive component, or mixtures thereof. *The preferred mucoadhesive polymers are cross-linked homopolymers and copolymers based on acrylic acid and methacrylic acid, especially the Carbopol and polycarbophil polymers supplied by B.F. Goodrich, and Eudragit polymers supplied by Rohm-Haas; most preferred are Carbopol, Noveon AA1, and Eudragit L-100. [emphasis supplied]*"

Applicants do not dispute that either one or both of the above-mentioned polymers, i.e. dermatan and hyaluronic acid, are within the scope of applicants' claims 18, 19, 21-32, 34-39, 41-43 and 45-46.

However, in the first place, Jacob et al. is totally devoid of any mention of the remaining members of applicants' Markush group, namely: chondroitin, keratan, heparin, acemannan, and nasally acceptable salts thereof; and in particular fails to teach chondroitin or its salt, which is specifically required by applicants' claims 20, 33, 35, 40, 44-45 and 47.

Moreover, even while mentioning dermatan and hyaluronic acid, there is simply no teaching by Jacob et al. to use either of those components specifically in combination with propylene glycol.

The single mention by Jacob et al. of propylene glycol occurs in a separate recitation of possible humectants for use in the formulations of the reference (of which in fact, glycerin, rather than propylene glycol, is indicated to be preferred), and in the context of a broad brush recitation of several different functional categories of potential excipients (Pars. 69-76). The Examiner surely acknowledges the multitudes of combinations of excipients that are possible in selecting from these different categories. It is long-established in the patent law that the Examiner is not permitted to "pick and choose" from the prior art to arrive at applicants' claimed formulations.

Furthermore, the Examiner may not construct an obviousness rejection by picking and choosing elements of a reference in complete disregard of the contrary preferences expressed in the reference. The preference of Jacob et al., as stated in the specification and implicit in the

examples, is not to use hyaluronic acid or dermatan as a mucoadhesive, but rather homopolymers and copolymers based on acrylic acid and methacrylic acid, and furthermore, not to use propylene glycol as a humectant, but rather glycerin (Pars. 70, 73; Examples 1,2, and 7). In order to reject applicants' claims as being obvious over Greve et al. in view of Jacob et al., the Examiner must ignore the clear teaching and direction of the reference to use mucoadhesive polymers which are different from applicants', and to use a glycerin as a viscosity enhancer/humectant over propylene glycol.

Finally, the obviousness rejection of record is improper for the reason that the reference in Jacob et al. to propylene glycol is not even relevant to nasal compositions since Jacob et al. refer to it solely for the purpose "to provide a pleasant mouth-feel in *oral applications*" (Par. 73). Jacob et al. is simply devoid of any teaching or suggestion to combine a mucopolysaccharide with propylene glycol to improve the properties of a *nasal formulation*, as claimed by applicants.

It is further pointed out that Jacob et al., like Greve et al., require a preservative (benzyl alcohol or phenoxyethanol) in the working examples; and therefore fail to suggest the preservative-free compositions of applicants' claims 27, 46 and 47.

Applicants submit that the obviousness rejection of record is improper for the reason that Greve et al. teach against use xylometazoline or oxymetazoline without a pantotheno; and Jacob et al. fail to provide a suggestion or motivation to prepare the combination of the recited mucopolysaccharides of applicants' claims with propylene glycol in a nasal composition.

Accordingly, the obviousness rejection of record of claims 18-24 and 26-34 over Greve et al. in view of Jacob et al. should be withdrawn.

Claim 25 was also rejected as being prima facie obvious over Greve et al. in view of Jacob et al. as applied to claims 18-24 and 26-3[4] above, and further in view of the Shahinian reference of record, US 2004/0018252 ("Shahinian"), teaching self-preserved antibacterial nasal compositions with lavender oil. The Examiner acknowledges that Greve et al. and Jacob et al. lack the express teaching of a formulation comprising essential plant oil, but states that the deficiency is cured by Shahinian. However, applicants submit that claim 25 is not obvious over Greve et al. combined with Jacob et al. for the reasons indicated hereinabove in connection with claims 18-24 and 26-34, and Shaninian does not cure the deficiency with respect to claim 25 merely by teaching the addition of lavender oil to a nasal composition.

Accordingly, reconsideration of the rejections of record under 35 USC 112, second paragraph, and 35 USC 103, and early allowance of claims 18-47, are respectfully solicited.

Applicants at this time wish to bring to the Examiner's attention commonly assigned co-pending Application No. 10/196,520, relating to nasal solutions, that has published as US20020193417, copy attached.

Respectfully submitted,

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 4/6/07
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Enclosures as noted

The
Condensed Chemical
Dictionary

EIGHTH EDITION

Revised by

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Coeditor, Encyclopedia of Chemistry



VAN NOSTRAND REINHOLD COMPANY

NEW YORK CINCINNATI TORONTO LONDON MELBOURNE

essential oil. A volatile oil derived from the leaves, stem, flower or twigs of plants, and usually carrying the odor or flavor of the plant. Chemically, they are often principally terpenes (hydrocarbons), but many other types also occur. Essential oils (except for those containing esters) are unsaponifiable. Some are nearly pure single compounds, as oil of wintergreen, which is methyl salicylate. Others are mixtures, as turpentine oil (pinene, dipentene), and oil of bitter almond (benzaldehyde, hydrocyanic acid). Some contain resins in solution and are called oleoresins or balsams (q.v.).

Properties: Pungent taste, and odor, usually nearly colorless when fresh, but becoming darker and thick on exposure to the air; optically active; sp. gr. 0.850-1.100. Soluble in alcohol, carbon disulfide, carbon tetrachloride, chloroform, petroleum ether and fatty oils; insoluble in water, except for individual constituents of some oils which may be partially water-soluble, resulting in a loss of these constituents during steam distillation.

Methods of extraction: (a) By steam distillation; (b) by pressing (fruit rinds); (c) by solvent extraction; (d) by maceration of the flowers and leaves in fat and treating the fat with a solvent; (e) by enfleurage (q.v.).

Uses: Perfumery; flavors; thinning precious metal preparations used in decorating ceramic ware.

See also terpeneless oil, and specific entries. Further information can be obtained from the Essential Oil Association of U.S.

"Esskol."¹⁸⁴ Trademark for modified linseed oils used in redwood finishes, varnishes, and enamels.

"Essotane."¹⁸¹ Trademark for liquefied petroleum gases for domestic and industrial uses.

"Essowax."¹⁸¹ Trademark for fully refined paraffin wax available in slabs and in liquid form in wide range of melting points and hardness.

"Estan."¹⁸¹ Trademark for light colored, general purpose, lime-base greases. Available in wide range of consistencies and suitable for all methods of application. Made with an oil having a minimum of internal friction and bearing drag.

"Estane" Polyurethane Materials.¹¹⁸ Trademark for thermoplastic polyester and polyether urethane elastomers which provide good physical and chemical properties without curing. Extremely tough and abrasion resistant with high tensile strength at high ultimate elongation; good solvent resistance, particularly to gasoline; low air permeability, and exceptional low-temperature flexibility.

Uses: Wire and cable jacketing, fuel hose and tanks, belting, shoe heels, coated fabrics, free film, adhesives.

"Estar."¹¹⁵ Trademark for polyester film base.

ester. An organic compound corresponding in structure to a salt in inorganic chemistry. Esters are considered as derived from the acids by the exchange of the replaceable hydrogen of the latter for an organic alkyl radical. Esters are not ionic compounds, but salts usually are.

See also fatty ester.

ester gum. Hard, semisynthetic resin produced by esterification of natural resins (especially rosin) with polyhydric alcohols (principally glycerol, but also pentaerythritol). Flash point 375° F. Combustible.

Grades: By color; also as gum rosin or wood rosin. **Containers:** 300-lb barrels and drums; multiwall paper sacks.

Uses: Paints, varnishes, and cellulosic lacquers.

"Esteron."¹²³³ Trademark for a series of weed and brush control products; they are formulated esters of 2,4-D and 2,4,5-T.

Hazard: Moderately toxic.

"Estinyl."¹³²¹ Trademark for ethinyl estradiol.

"Estonate."¹⁸⁸⁸ Trademark for a DDT insecticide as both wettable powders and emulsifiable solutions.

"Estonmite."¹⁸⁸ Trademark for para-chlorophenyl para-chlorobenzene sulfonate; miticide; available as a dust base, wettable powder and emulsifiable solution; used as an ovicide, specific against the eggs of spider mites.

"Estonox."¹⁸⁸ Trademark for toxaphene in a dust base, wettable powder and in a stabilized emulsifiable carrier; used for control of insects on cotton, seed alfalfa, sugar beets, beans and potatoes.

Hazard: Probably toxic. See toxaphene.

estradiol C₁₈H₂₄O₂. A female sex hormone. It occurs in two isomeric forms, alpha and beta. Beta-estradiol has the greatest physiological activity of any naturally occurring estrogen. The alpha form is relatively inactive. Commonly used preparations, are the benzoate, cypionate, dipropionate, and valerate, as well as ethinylestradiol (q.v.).

Properties of beta form: White or slightly yellow; small crystals or crystalline powder; odorless; m.p. 173-179°C; stable in air; almost insoluble in water; soluble in alcohol, acetone, dioxane, and in solutions of alkali hydroxides; sparingly soluble in vegetable oils.

Derivation: Isolation from human and mare pregnancy urine; commercial synthesis from cholesterol or ergosterol.

Grade: N.F. (beta form).

Use: Medicine.

estragole (chavicol methyl ether; methyl chavicol)

C₆H₄(C₃H₅)(OCH₃).

Properties: Colorless liquid; anise odor; sp. gr. 0.965-0.975 (20/4°C); (n_D 17.5/D) 1.5230; b.p. 216°C. Soluble in alcohol and chloroform. Low toxicity.

Occurrence: In estragon oil; basil oils; anise bark oil, and others.

Uses: Perfumes; flavors.

estragon oil (tarragon oil).

Properties: Colorless to yellowish-green essential oil; anise-like odor; aromatic but not sweet taste. Keep well stoppered. Solubility in alcohol: in 6 to 11 vols and more of 80% alcohol; in 1 vol and more of 90% alcohol. Sp. gr. 0.914-0.956 (25°C); optical rotation +2° to +9°; refractive index 1.502 to 1.514; acid value up to 1; ester value 1 to 9, after acetylation 15. Low toxicity.

Derivation: Distilled from the flowering herb of artemisia dracunculus L.

Containers: Glass bottles; copper flasks.

Grades: Technical: F.C.C. (as tarragon oil).

Use: Flavoring.

"Estrex."¹¹⁵² Trademark for a series of methyl, butyl, and propyl, glyceryl, and polyethylene glycol esters of fatty acids.

Uses: Adhesives, agricultural sprays, aluminum rolling, antioxidants, cosmetics, cutting oils, detergents,

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ACLM/"essential oil": 537 patents.

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ACLM/"essential oil"

PAT. NO.	Title
1 7,182,950	Nano-sized self-assembled liquid dilutable vehicles
2 7,169,595	Thermotolerant phytase for animal feed
3 7,169,424	Mold inhibitor having reduced corrosiveness
4 7,148,187	Low residue cleaning composition comprising lactic acid, nonionic surfactant and solvent mixture
5 7,147,876	Compositions for removal of toxins
6 7,138,129	Skin care compositions
7 7,128,933	Composition and method for the treatment of personal odors
8 7,128,109	Essential oil reclaim apparatus, and method of use
9 7,118,770	Artemisia extract for treating allergies
10 7,108,834	Device for producing negative ion fragrance
11 7,108,198	Nasal aromatherapy dispenser clip
12 7,105,190	Products comprising an isothiocyanate preservative system and methods of their use
13 7,087,255	Chewing gums that provide breath freshening characteristics
14 7,074,439	Preparation of essential oil compositions for potable liquid disinfection
15 7,074,264	Foaming aqueous composition, use thereof and process for temporary demarcation of regulation distances in sports
16 PP16,712	Citral rich high yielding lemongrass plant 'Nima' of Cymbopogon flexuosus
17 7,048,953	Methods and apparatus to prevent, treat and cure infections of the human respiratory system by pathogens causing severe acute respiratory syndrome (SARS)
18 7,041,304	Thermotropic liquid crystal polymer microcapsules, a method for preparing the same, and cosmetic compositions containing the same
19 7,037,367	Concrete surface retarders
20 7,032,601	Encapsulated materials
21 7,030,079	Fragrance composition exhibiting varying olfactive characteristics when applied on different persons
22 7,017,735	Dispensing cap with capsule for container
23 7,011,093	Microencapsulated fragrances and methods of coating microcapsules

- 24 [7,008,913](#)  [Aromatic substituted nonionic surfactants in soil prevention, reduction or removal in treatment zones](#)
- 25 [7,004,313](#)  [Disposable dispenser with fragrance delivery system](#)
- 26 [7,001,880](#)  [Method of collection of fragrance ingredient, perfume composition containing this fragrance ingredient and cosmetics containing this fragrance ingredient](#)
- 27 [7,000,852](#)  [Evaporative scent burner provided with a gypsum evaporative base](#)
- 28 [6,986,898](#)  [Synergistic and residual pesticidal compositions containing plant essential oils with enzyme inhibitors](#)
- 29 [6,974,799](#)  [Compositions containing mixtures of tetrapeptides and tripeptides](#)
- 30 [6,974,091](#)  [Dispensing means](#)
- 31 [6,951,833](#)  [Anti-microbial compositions](#)
- 32 [6,939,553](#)  [Treated substrate with improved transfer efficiency of topical application](#)
- 33 [6,932,986](#)  [Essential oil mixture for miticide, miticide composition, and spray for miticide](#)
- 34 [6,929,810](#)  [Preparation of essential oil compositions for portable liquid disinfection](#)
- 35 [6,927,309](#)  [Sulfur compounds and intermolecular compounds containing the same as the component compounds](#)
- 36 [6,921,745](#)  [Bactericidal composition comprising polylysine and a plant essential oil](#)
- 37 [6,919,095](#)  [Method of providing an essential oil extract of capsicum, and the extract](#)
- 38 [6,911,436](#)  [Pharmaceutical composition of complex carbohydrates and essential oils and methods of using the same](#)
- 39 [6,911,119](#)  [Simple portable mini distillation apparatus for the production of essential oils and hydrosols](#)
- 40 [6,887,839](#)  [Solid alkylbenzene sulfonates and cleaning compositions having enhanced water hardness tolerance](#)
- 41 [6,884,763](#)  [Waterless hand cleaner containing plant derived natural essential oil](#)
- 42 [6,884,438](#)  [Method for preparing vesicular nanocapsules](#)
- 43 [6,872,754](#)  [Method for processing elastomers](#)
- 44 [6,866,841](#)  [Non-endocrine disrupting cytoprotective UV radiation resistant substance](#)
- 45 [PP15,595](#)  [Cymbopogon plant named 'RLJCC1'](#)
- 46 [6,861,060](#)  [Personal care formulations](#)
- 47 [6,860,234](#)  [Animal litter composition containing silica gel and methods therefor](#)
- 48 [6,852,343](#)  [Antiadipose topical treatment composition based on garlic bulbs extracts, and cosmetic and therapeutic uses](#)
- 49 [6,849,276](#)  [Liquid composition with fungicide, bactericidal and bacteriostatic activity](#)
- 50 [6,846,498](#)  [Antimicrobial composition formulated with essential oils](#)
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